IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

HOPE HUERTA as Next Friend and Parent of BLANCA M. VALDEZ-HUERTA, a minor,

Plaintiffs,

vs. Civ. No. 09-485 RHS/LFG

BIOSCRIP PHARMACY SERVICES, INC., and DOES 1-25,

Defendants.

**MEMORANDUM OPINION AND ORDER**

THIS MATTER is before the Court on Defendant BioScrip Pharmacy Services, Inc.'s *Motion for Summary Judgment*, filed May 24, 2010 [Doc. 182], brought pursuant to FED. R. CIV. P. 56. Having the considered the parties' submissions, the record, and the applicable law, the Court will grant the motion.

**I. Legal standard**.

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c)(2). Under Rule 56(c), "the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). Rather, "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Id.* at 248. A dispute about a material fact is genuine only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

The Court must "view the evidence and draw any inferences in a light most favorable to the party opposing summary judgment, but that party must identify sufficient evidence which would require submission of the case to a jury." *Williams v. Rice*, 983 F.2d 177, 179 (10th Cir. 1993) (citing *Anderson*, 477 U.S. at 249-52). The requirement of viewing " the evidence in the light most favorable to the non-moving party . . . does not mean, however, that we may disregard undisputed evidence that favors the moving party." *Zamora v. Elite Logistics, Inc.*, 478 F.3d 1160, 1168 (10th Cir. 2007). Summary judgment is properly regarded

> as an integral part of the Federal Rules as a whole, which are designed "to secure the just, speedy and inexpensive determination of every action." . . . Rule 56 must be construed with due regard not only for the rights of persons asserting claims and defenses that are adequately based in fact to have those claims and defenses tried to a jury, but also for the rights of persons opposing such claims and defenses to demonstrate in the manner provided by the Rule, prior to trial, that the claims and defenses have no factual basis.

*Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986). As the moving party, BioScrip bears the initial burden of showing the absence of a genuine issue of material fact. *See id.* at 325. "When, as in this case, the moving party does not bear the ultimate burden of persuasion at trial, it may satisfy its burden at the summary judgment stage by identifying a lack of evidence for the nonmovant on an essential element of the nonmovant's claim." *Cassara v. DAC Serv., Inc.*, 276 F.3d 1210, 1212 (10th Cir. 2002) (internal quotation marks omitted). The burden then shifts to the Plaintiffs to come forward with admissible evidence showing that there is a genuine issue of material fact on that element. *See Bacchus Indus., Inc. v. Arvin Indus., Inc.*, 939 F.2d 887, 891 (10th Cir. 1991).

**II. Undisputed facts.**

In 2003, seven-year-old Blanca Valdez-Huerta received a kidney transplant. Thereafter, she took medications, including tacrolimus and Cellcept, to suppress her immune system and help prevent rejection of the implant. Blanca was hospitalized in February 2006 after a "series of

pneumonias that didn't clear with antibiotics." Doc. 175, Ex. B at 6. On March 8, 2006, Dr. John Brandt and Blanca's other treating nephrologists substituted Imuran for the Cellcept. *See id.* at 5. Blanca had been taking Cellcept since the implant, but her doctors took her off of it because they thought the Cellcept was "oversuppressing [production] of white blood cells . . . that may have led to an increased risk of infection." Doc. 201, Ex. 3 at 3 (Dr. Brandt's Depo.); Doc. 175, Ex. C at 12 (Dr. Steven Alexander's deposition, stating that a "low white blood cell count . . . [is] the most common side effect of CellCept."). Imuran is also an immunosuppressant that "suppresses the immune system less" than Cellcept. Doc. 181, Ex. 2 at 6 (Dr. Craig Wong's Depo.). 2, 4-5. Dr. Steven Alexander, another of Blanca's treating nephrologists testified that, "if Imuran is inadequate in combination with the [tacrolimus] to prevent rejection, then you could see rejection from a change from [tacrolimus]/Cellcept to [tacrolimus]/Imuran." Doc. 175, Ex. C at 9.

In the spring of 2006, based on "recipes" provided by the national Children's Hospital pharmacy guide, BioScrip compounded from capsules, and dispensed as a liquid suspension, the prescribed tacrolimus that Blanca orally ingested. Doc. 182, Ex. 5 at 2. The Plaintiffs' pharmaceutical expert, Dr. Randall Tackett, testified that he saw "a lot of sloppy record-keeping" when he looked at BioScrip's pharmacy records. Doc. 174, Ex. A at 5. This criticism was based, in part, on difficulty a former employee had, at his deposition, in "follow[ing] batch numbers;" on finding "a quality assurance that's not signed off on;" and "dates that are not complete" on some of the pharmaceutical records. *Id.* at 6. Based on his experience, Dr. Tackett testified that compounding errors involving capsules, as opposed to powders, most often occur in "miscounting" the capsules. *Id*. And based on his experience, Dr. Tackett stated that "poor record-keeping . . . reflects poor laboratory procedures and skills," *id.* at 7-8. But Dr. Tackett stated that he could see no error in BioScrip's calculations used to compound Blanca's medication. Doc. 182, Ex. 10 at 2.

It is undisputed that, in 2006, BioScrip used a capsulated form of tacrolimus manufactured and distributed by Astellas Pharma U.S. Inc. ("Astellas") to compound its tacrolimus suspension. The Plaintiffs voluntarily dismissed Astellas as a Defendant because there was no evidence that the tacrolimus Astellas manufactured and supplied to BioScrip was subpotent or had been the subject of any recall. *See* Doc. 39; Doc. 182, Ex. 1 at 2. And the Plaintiffs have produced no direct evidence, from testing the suspension Blanca ingested or examining the compounding records, for example, that BioScrips' April or May 2006 formulations were, in fact, subpotent or improperly compounded.

"In April 2006 Blanca's prescription for tacrolimus suspension was filled from tacrolimus suspension Batch #37, which also supplied the prescriptions for three patients other than Blanca." Doc. 182 at 5, ¶ 12; *see* Doc. 202 at 6 (disputing this fact only "to the extent it implies that the tacrolimus compounded, dispensed . . . and ingested by Blanca was not subpotent"). "BioScrip has received no reports of adverse reaction or harm suffered by any of the other three patients who received their tacrolimus suspension from Batch #37." Doc. 182 at 5, ¶ 13[1].

[1] The Plaintiffs objected to this statement, asserting that it is disputed based on their contentions that the statement "lacks personal and first-hand knowledge; [and] lacks foundation;" that BioScrip had allegedly withheld evidence of Class 1 errors that were the subject of a motion to compel; that the term 'reports' was "vague and ambiguous;" and that the statement was more prejudicial than probative because it lacked credibility in that the Plaintiffs had reported to BioScrip their belief that Blanca's rejection was caused by subpotent tacrolimus. The Court concludes that the statement is, in fact based on personal knowledge and does not lack foundation. *See* Doc. 182, Ex. 8. Further, the Plaintiffs have admitted that BioScrip had responded to its discovery request to produce all documents showing compounding errors for 2006, *see* Doc. 173 at 2, and the Court denied the motion to compel reports from other years as untimely. *See* Doc. 206 at 3. The Court further concludes that the term "reports" is not vague or ambiguous and that the statement is not unfairly prejudicial or uncredible, since the statement refers only to other patients who also ingested tacrolimus or other medications that BioScrip compounded and/or dispensed in 2006. Accordingly, the Court finds this fact to be undisputed.

In May 2006 Blanca experienced a severe and acute rejection of her transplanted kidney[2]. When she was admitted to the hospital the afternoon of May 15, 2006, Blanca's creatinine levels were 9, up from only .6 a month before. *See* Doc. 175, Ex. C. at 8; Doc. 181, Ex. 2 at 3. She had been vomiting "one to two times per night" for three nights before her admission on the afternoon of May 15, and she continued to vomit through May 16. *See* Doc. 175, Ex. B at 5-6. There was no way to know what Blanca's tacrolimus levels were on May 15 because no "level was drawn on that day." *Id.* at 6. On May 15, Dr. Brandt, the admitting physician, decreased Blanca's tacrolimus ingestion from 5 milligrams every twelve hours to two milligrams every twelve hours until he could obtain a laboratory report showing her tacrolimus blood level, which was measured on May 17. *See* Doc. 182, Ex. 12 at 6. Dr. Minnie Sarwal testified that "it's possible" that this reduction in tacrolimus ingestion was part of the reason that Blanca's tacrolimus blood level was low on May 17. *See* Doc. 182, Ex. 13, at 3. On May 17, 2006, Blanca's tacrolimus level was 2.5. *See* Doc. 198, Ex. A at 2. No laboratory testing of Blanca's tacrolimus levels had been performed before May 15 except for her monthly testing on April 12, which was apparently normal at 5.4. *See id.* Dr. Brandt testified that several things may effect the tacrolimus level in a transplant patient's system, including other prescription drugs, "whether you're taking it reliably," liver enzymes, hematocrit and albumin levels, and dehydration. Doc. 201, Ex. 3 at 3. He also testified that "vomiting [can] affect the absorption of tacrolimus into the system." *Id.*

Dr. Craig Wong, another of Blanca's treating nephrologists, described Blanca's rejection as a "catastrophe," usually seen when there is *no* immunosuppression, and he testified that "not getting any immunosuppresion" could include "not taking" the immunosuppressant medications; "taking

[2] Blanca partially recovered from this rejection, but suffered another acute rejection in 2007 and had to undergo a second transplant.

it and not having the proper drug," as when the child is getting someone else's prescription by mistake; and "discontinuation of medications." Doc. 198, Ex. A at 3-4. Dr. Wong testified that teenagers who are noncompliant with taking their immunosuppressant medications even 10-25% of the time can still "kind of manage to do okay." Doc. 181, Ex. 2 at 3. Dr. Wong stated that he had "hardly seen any severe acute rejections except for the cellular ones where the teens stopped taking their medicines . . . for like a month." Doc. 175, Ex. B at 7. Dr. Steven Alexander, another of Blanca's treating nephrologists, testified that nonadherence in taking the tacrolimus is the most common reason for inadequate immunosuppression. Doc. 201, Ex. 6 at 6-7.[3]

Dr. Wong testified that dehydration may impact tacrolimus absorption if "you've got kidney failure;" that "there can be interactions with antibiotics;" and that "vomiting can impact absorption rates of tacrolimus." Doc. 175, Ex. B at 4-5. Dr. Wong testified that it was "possible" that the vomiting she experienced had affected Blanca's absorption of tacrolimus and that he could not say, to a "reasonable degree of medical probability" that the vomiting had *not* compromised Blanca's tacrolimus levels because "without the level, there is no way to know." *Id.* at 6. He testified that, based on the severity of Blanca's rejection, he believed that "something went terribly wrong with her immunosuppressant medication." *See id.* at 10.

Dr. Wong also testified that Blanca's high creatinine levels on May 15, 2006 could be due to a "number of possibilities," including "rejection, . . . obstruction of the kidney, . . . return of old kidney disease into the transplant or plain inadequate blood flow to the kidney . . . [from]

[3] Although the parties do not discuss it, the pharmacy records the Plaintiffs submitted in response to the motion for summary judgment show that Blanca's thirty-day prescription for tacrolimus suspension she received on 9/22/05, which should have been refilled on 10/22/05, was not refilled until 10/31/05; that her January prescription, which should have been refilled on 1/20/06, was not refilled until 1/23/06; and that her February prescription, which should have been refilled on 2/22/06, was not refilled until 2/27/06. *See* Doc. 201, Ex. 2 at 1-2.

dehydration or clots." *Id.* But Blanca had no obstruction and had "a good blood flow to her kidney," and she had been doing well for a long time before the rejection, so he deduced that there was "some type of catastrophe with her immunosuppression." Doc. 181, Ex. 2 at 3.

Dr. Wong testified that, in May 2007, Blanca's medical records showed that "she had undetectable levels" of tacrolimus and that the doctors were concerned "that her mother wasn't dosing her properly." Doc. 181, Ex. 2 at 3. According to the medical records, in May 2007 Dr. Brandt reported:

> In the past 2 weeks Blanca has had difficulty with achieving adequate blood levels of Rapamycin and [tacrolimus]. During this time multiple family members have been responsible for medication administration and we suspect this has been inadequate. Here in the hospital on her standard medication doses, her [tacrolimus] level was most recently 8.7 and a Rapamycin level 5.8.

Doc. 175, Ex. D at 6.

The basis of the Plaintiffs' lawsuit is that, as a result of Blanca's ingestion of BioScrip's allegedly subpotent tacrolimus, she rejected her transplanted kidney in May 2006.

**II. Analysis**

As noted above, BioScrip has demonstrated that there is no direct evidence that the tacrolimus suspension it compounded for Blanca was subpotent or otherwise defective, and that there were several other undisputed factors that could have contributed to Blanca's transplant rejection. The continuing vitality of this case, therefore, depends upon a single issue: whether the Plaintiffs have met their burden to come forward with sufficient, admissible, medical evidence to show that BioScrip compounded and dispensed subpotent tacrolimus that caused Blanca kidney-transplant rejection such that a reasonable jury could return a verdict in favor of the Plaintiffs. The Court concludes that they have not met their burden.

The Court has recently ruled that, because their opinions are not based on known facts or

other "good grounds;" because their opinions relied at least in part on incorrect assumptions or incorrect information from the Plaintiffs' attorneys; and because they could not rule out the most common cause of a low level of tacrolimus in Blanca's system, which is nonadherence to the prescription regimen, none of the Plaintiffs' medical experts may testify to a reasonable degree of medical probability that the ultimate cause of Blanca's rejection was subpotency or inadequate compounding of Blanca's tacrolimus suspension. *See* Docs. 224 and 226.

The Court also has ruled, however, that BioScrip may present the expert-witness testimony of Dr. Chris Clardy. *See* Doc. 223. Dr. Clardy's testimony is based on four known facts: (1) Blanca was changed from CellCept to Imuran, a less strong immunosuppressant, two months before her rejection; (2) Blanca was vomiting for 3 days before she was hospitalized and her creatinine levels were checked, and she vomited for 5 days before her tacrolimus levels were checked; (3) the severity and acuteness of Blanca's rejection is usually seen when there is little or no immunosuppression; and (4) a year later, Blanca was again hospitalized with no detectable levels of immunosuppressant medication in her system, but when Blanca was administered the prescribed dosages by hospital staff, her immunosuppressant levels returned to normal. Dr. Clardy also relied, in developing his opinion, on medical research showing that 30-70% of pediatric transplant patients are non-adherent in taking medications as prescribed.

Dr. Clardy testified that, although it was theoretically "possible" that Blanca's transplant rejection could have been caused by an improper preparation of the tacrolimus suspension, there was a 75 to 80 percent "probability" that the cause of Blanca's rejection was a combination of non-adherence or some other reason for insufficient levels of tacrolimus in her system other than subpotency, plus the change from Cellcept to Imuran. *See* Doc. 200, Ex. A at 2-3. When Dr. Clardy's opinion is combined with the undisputed fact that the other three patients taking BioScrip's

tacrolimus suspension from the same batch as Blanca did not report any issues with the tacrolimus BioScrip compounded, no reasonable jury could find that the tacrolimus was defective or caused Blanca's rejection.

Because there is no other admissible expert-medical-witness testimony regarding the ultimate causation of Blanca's transplant rejection to contradict Dr. Clardy's testimony, and no direct or indirect evidence of subpotency of BioScrip's tacrolimus suspension, the Court concludes that the Plaintiffs cannot establish that (1) the tacrolimus BioScrip marketed and dispensed was subpotent or defective; (2) BioScrip's compounding of the tacrolimus suspension failed to meet the standard of care; (3) BioScrip made any misrepresentations or concealed any information about the quality and efficacy of the tacrolimus it dispensed; (4) BioScrip's tacrolimus was not fit for human consumption; (5) Blanca's low levels of tacrolimus on May 17, 2006 were caused by BioScrip's marketing or dispensing of a defective product; or (6) Blanca's transplant rejection and resulting injuries were caused by ingestion of subpotent tacrolimus. Because the admissible evidence is not sufficient for a reasonable jury to return a verdict for the Plaintiffs on any of their claims, summary judgment must be granted in favor of BioScrip on all counts.

**IT IS ORDERED** that BioScrip's *Motion for Summary Judgment* [Doc. 182] is GRANTED, and judgment is entered in favor of BioScrip.

Robert Hayes Scott

ROBERT HAYES SCOTT
UNITED STATES MAGISTRATE JUDGE
Presiding by Consent